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31/573, A61P 37/08

SUGIBAYASHI, Nobuya [JP/JP]; 4-4-13, Miyano-hara,
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(21) International Application Number: PCT/JP00/05200

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(25) Filing Language: English

(26) Publication Language: English

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DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR,
HU, ID, IL, IN, IS, JP, KE, KG, KR, KZ, LC, LK, LR, LS,
LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO,
NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR,
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(84) Designated States (*regional*): ARIPO patent (GH, GM,
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patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European
patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,
IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG,
CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

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suihiro [JP/JP]; 1-13, Saiwaicho, Utsunomiya-shi, Tochigi
320-0848 (JP). ONOZAKI, Tomohisa [JP/JP]; 2-38-4,
Toyosatodai, Utsunomiya-shi, Tochigi 320-0003 (JP).

Published:

- With international search report.
- Before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments.

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: AQUEOUS NASAL FORMULATION

(57) Abstract: The present invention provides an aqueous nasal formulation comprising beclomethasone dipropionate anhydrate
for use in the treatment of respiratory disorders.

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WO 01/10409 A1

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

SUZUYE, Takehiko et al.
SUZUYE & SUZUYE
7-2 Kasumigaseki 3-chome,
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Tokyo 100-0013
JAPON.

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PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing
(day/month/year) 01.06.2001

Applicant's or agent's file reference
00S0828P

IMPORTANT NOTIFICATION

International application No.
PCT/JP00/05200

International filing date (day/month/year)
03/08/2000

Priority date (day/month/year)
07/08/1999

Applicant

GLAXO WELLCOME KABUSHIKI KAISHA et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

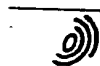
4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized officer

Longo, E

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| | | | |
|--|--|---|--|
| Applicant's or agent's file reference 00S0828P | | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/JP00/05200 | International filing date (day/month/year) 03/08/2000 | Priority date (day/month/year) 07/08/1999 | |
| International Patent Classification (IPC) or national classification and IPC A61K9/08 | | | |
| Applicant GLAXO WELLCOME KABUSHIKI KAISHA et al. | | | |
| <p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p> | | | |
| <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p> | | | |
| Date of submission of the demand 18/01/2001 | | Date of completion of this report 01.06.2001 | |
| Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | | Authorized officer Uhl, M Telephone No. +49 89 2399 8654  | |

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/JP00/05200

I. Basis of the report

1. With regard to the elements of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17):*

Description, pages:

1-12 as originally filed

Claims, No.:

1-9 as originally filed

Drawings, sheets:

1/5-5/5 as originally filed

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/JP00/05200

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
☒ claims Nos. 8, as far as industrial applicability is concerned.

because:

- ☒ the said international application, or the said claims Nos. 8 relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

- ☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims 1-9

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/JP00/05200

| | | | |
|-------------------------------|------|--------|-------|
| | No: | Claims | |
| Inventive step (IS) | Yes: | Claims | 1-9 |
| | No: | Claims | |
| Industrial applicability (IA) | Yes: | Claims | 1-7,9 |
| | No: | Claims | |

2. Citations and explanations
see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/JP00/05200

Re Item III**Non-establishment of opinion with regard to novelty, inventive step and
Industrial applicability**

Claim 8 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of this claim (Article 34(4)(a)(i) PCT).

**Re Item V Reasoned statement under Article 35(2) with regard to novelty,
inventive step or industrial applicability; citations and explanations supporting
such statement**

For the assessment of the present claim 8 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment like claimed in claim 7.

Novelty(Art.33(2) PCT):

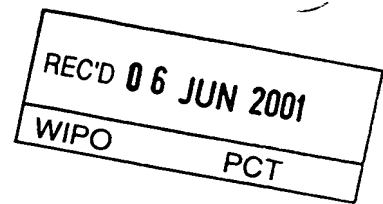
A pharmaceutical formulation which comprises an aqueous solution of carboxymethylcellulose sodium, glycerol, propylene glycol and polyoxyethylene (20) sorbitan monooleate, containing suspended therein particulate microcrystalline cellulose and beclomethasone dipropionate anhydrate and dextrose, phenylethyl alcohol, benzalkonium chloride, disodiumhydrogenorthophosphate and citric acid is not disclosed in the prior art. Subject matter of claims 1-9 is therefore regarded to be novel over the prior art.

Inventive Step (Art. 33(3) PCT):

Closest prior art is regarded to be EP-A-780127. Difference to the present application: The prior art composition lacks several of the ingredients. Problem was to find an improved preparation. This problem was solved by the claimed combination of ingredients. This solution is not regarded as being obvious for the skilled person, as not specifically envisaged or recommended in the art. Thus subject matter of claims 1-9 is regarded to involve an inventive step.

PATENT COOPERATION TREATY

PCT



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| | | |
|--|--|---|
| Applicant's or agent's file reference 00S0828P | | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |
| International application No. PCT/JP00/05200 | International filing date (day/month/year) 03/08/2000 | Priority date (day/month/year) 07/08/1999 |
| International Patent Classification (IPC) or national classification and IPC A61K9/08 | | |
| Applicant GLAXO WELLCOME KABUSHIKI KAISHA et al. | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 5 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

| | |
|---|---|
| Date of submission of the demand 18/01/2001 | Date of completion of this report 01.06.2001 |
| Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | Authorized officer Uhl, M Telephone No. +49 89 2399 8654  |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/JP00/05200

I. Basis of this report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):
Description, pages:

1-12 as originally filed

Claims, No.:

1-9 as originally filed

Drawings, sheets:

1/5-5/5 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/JP00/05200

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

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☐ the entire international application.

☒ claims Nos. 8, as far as industrial applicability is concerned.

because:

☒ the said international application, or the said claims Nos. 8 relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

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☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims 1-9

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/JP00/05200

| | | | |
|-------------------------------|------|--------|-------|
| | No: | Claims | |
| Inventive step (IS) | Yes: | Claims | 1-9 |
| | No: | Claims | |
| Industrial applicability (IA) | Yes: | Claims | 1-7,9 |
| | No: | Claims | |

2. Citations and explanations
see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claim 8 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of this claim (Article 34(4)(a)(i) PCT).

Re Item V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

For the assessment of the present claim 8 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment like claimed in claim 7.

Novelty(Art.33(2) PCT):

A pharmaceutical formulation which comprises an aqueous solution of carboxymethylcellulose sodium, glycerol, propylene glycol and polyoxyethylene (20) sorbitan monooleate, containing suspended therein particulate microcrystalline cellulose and beclomethasone dipropionate anhydrate and dextrose, phenylethyl alcohol, benzalkonium chloride, disodiumhydrogenorthophosphate and citric acid is not disclosed in the prior art. Subject matter of claims 1-9 is therefore regarded to be novel over the prior art.

Inventive Step (Art. 33(3) PCT):

Closest prior art is regarded to be EP-A-780127. Difference to the present application: The prior art composition lacks several of the ingredients. Problem was to find an improved preparation. This problem was solved by the claimed combination of ingredients. This solution is not regarded as being obvious for the skilled person, as not specifically envisaged or recommended in the art. Thus subject matter of claims 1-9 is regarded to involve an inventive step.

INTERNATIONAL SEARCH REPORT

Intern. Application No
PCT/JP 00/05200

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/08 A61K31/573 A61P37/08

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-internal, WPI Data, PAJ, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|---|-----------------------|
| X | EP 0 780 127 A (PROCTER & GAMBLE) 25 June 1997 (1997-06-25) the whole document | 1-8 |
| A | & "Remington's pharmaceutical sciences 14th edition" page 1557 -page 1560; table 6 | 1-8 |
| X | WO 97 46243 A (PROCTER & GAMBLE) 11 December 1997 (1997-12-11) page 2, line 18 - line 36 page 4, line 12 -page 5, line 19 page 7, line 32 -page 8, line 18 page 9 -page 10; examples 1-4 claims 1-3 | 1-8 |
| A | & "Remington's pharmaceutical sciences 14th edition" page 1557 -page 1560; table 6 | 1-8 |
| | --- -/-- | |

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

18 December 2000

Date of mailing of the international search report

02/01/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl.
Fax: (+31-70) 340-3016

Authorized officer

Muller, S

INTERNATIONAL SEARCH REPORT

Intern. Application No

PCT/JP 00/05200

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|---|-----------------------|
| P, X | WO 99 49984 A (PIETERS JULIAN ROBERT ;WILKINSON ERIC (GB); LAWSON ROBERT ANDREW () 7 October 1999 (1999-10-07) page 2, line 8 -page 3, line 2 page 4, line 6 - line 12 page 5, line 1 -page 6, line 11 page 13 -page 14; example 3 | 1-8 |
| A | & "Remington's pharmaceutical sciences 14th edition" page 1557 -page 1560; table 6 ----- | 1-8 |
| A | "Aldecin nasal spray" MEDICAL JOURNAL OF AUSTRALIA, vol. 2, no. 9, 1979, page 494 XP000971559 page 494, column 3 ----- | 1-8 |

INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern. Application No

PCT/JP 00/05200

| Patent document cited in search report | | Publication date | Patent family member(s) | Publication date |
|---|---|---------------------|---|--|
| EP 0780127 | A | 25-06-1997 | NONE | |
| WO 9746243 | A | 11-12-1997 | AU 3153797 A BR 9709650 A EP 0954318 A JP 11511758 T | 05-01-1998 10-08-1999 10-11-1999 12-10-1999 |
| WO 9949984 | A | 07-10-1999 | AU 2741499 A | 18-10-1999 |

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| | | |
|--|--|--|
| Applicant's or agent's file reference 00S0828P | FOR FURTHER ACTION <small>see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.</small> | |
| International application No. PCT/JP 00/05200 | International filing date (day/month/year) 03/08/2000 | (Earliest) Priority Date (day/month/year) 07/08/1999 |
| Applicant GLAXO WELLCOME KABUSHIKI KAISHA | | |

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☒ None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/JP 00/05200

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K9/08 A61K31/573 A61P37/08

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|---|-----------------------|
| X | EP 0 780 127 A (PROCTER & GAMBLE) 25 June 1997 (1997-06-25) the whole document | 1-8 |
| A | & "Remington's pharmaceutical sciences 14th edition" page 1557 -page 1560; table 6 --- | 1-8 |
| X | WO 97 46243 A (PROCTER & GAMBLE) 11 December 1997 (1997-12-11) page 2, line 18 - line 36 page 4, line 12 -page 5, line 19 page 7, line 32 -page 8, line 18 page 9 -page 10; examples 1-4 claims 1-3 | 1-8 |
| A | & "Remington's pharmaceutical sciences 14th edition" page 1557 -page 1560; table 6 --- | 1-8 |
| | --- -/-- | |

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents :

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Z document member of the same patent family

Date of the actual completion of the international search

18 December 2000

Date of mailing of the international search report

02/01/2001

Name and mailing address of the ISA

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Authorized officer

Muller, S

INTERNATIONAL SEARCH REPORT

International Application No

PCT/JP 00/05200

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|---|-----------------------|
| P, X | WO 99 49984 A (PIETERS JULIAN ROBERT ; WILKINSON ERIC (GB); LAWSON ROBERT ANDREW () 7 October 1999 (1999-10-07) page 2, line 8 - page 3, line 2 page 4, line 6 - line 12 page 5, line 1 - page 6, line 11 page 13 - page 14; example 3 & "Remington's pharmaceutical sciences 14th edition" page 1557 - page 1560; table 6 ----- | 1-8 |
| A | | 1-8 |
| A | "Aldecin nasal spray" MEDICAL JOURNAL OF AUSTRALIA, vol. 2, no. 9, 1979, page 494 XP000971559 page 494, column 3 ----- | 1-8 |

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/JP 00/05200

| Patent document cited in search report | | Publication date | Patent family member(s) | Publication date |
|---|---|---------------------|---|--|
| EP 0780127 | A | 25-06-1997 | NONE | |
| WO 9746243 | A | 11-12-1997 | AU 3153797 A BR 9709650 A EP 0954318 A JP 11511758 T | 05-01-1998 10-08-1999 10-11-1999 12-10-1999 |
| WO 9949984 | A | 07-10-1999 | AU 2741499 A | 18-10-1999 |

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE
 in its capacity as elected Office

| | |
|--|--|
| Date of mailing (day/month/year) 02 May 2001 (02.05.01) | |
| International application No. PCT/JP00/05200 | Applicant's or agent's file reference 00S0828P |
| International filing date (day/month/year) 03 August 2000 (03.08.00) | Priority date (day/month/year) 07 August 1999 (07.08.99) |
| Applicant AKUTSU, Rika et al | |

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
 18 January 2001 (18.01.01)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

| | |
|---|--|
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35 | Authorized officer R. Forax Telephone No.: (41-22) 338.83.38 |
|---|--|